

### REMARKS

Upon receipt of the Office Action mailed December 2, 2008, Claims 1-29 were pending, of which Claims 5-6, 9-21 and 24-29 were withdrawn from further consideration as being drawn to non-elected subject matter, Claims 1-4, 22 and 23 were rejected and Claims 7 and 8 were objected to.

Applicants previously submitted an Amendment on April 2, 2009, wherein Claims 1-10, 12, 13-16, 18, 20 and 22-25 were amended. Specifically, the amendments to the claims limited the compounds of formula (I) and formula (Ia) therein to compounds wherein "R<sup>4a</sup> and R<sup>4b</sup> together form alkylidene or haloalkylidene."

In an Advisory Action mailed April 16, 2009, the Examiner noted that the Amendment filed on April 2, 2009, was not entered. The Examiner stated that the reason the amendments to the claims were not entered was because "[t]he claims as amended would require further search and/or consideration of the claimed invention."

On April 30, 2009, the undersigned attorney discussed with the Examiner her reasons for refusing entry of the previous Amendment. The Examiner explained that she had prepared her search strategy based on the choices of R<sup>2</sup> and R<sup>3</sup> reading on the elected species rather than the choice of R<sup>4a</sup> and R<sup>4b</sup>. Consequently, the Examiner contended that to amend the claims in the manner presented in the previous Amendment would have required that she expand her search to the other choices for R<sup>2</sup> and R<sup>3</sup> as set forth in the claims.

The instant Amendment addresses the Examiner's concerns raised during the discussion. Accordingly, Claims 1-6, 9-21, 23, 25 and 27-29 are cancelled herein. Claims 7, 8, 22, 24, and 26 are amended herein. Specifically, Claims 7, 8, 22, 24 and 26 are amended herein to limit the claimed compounds to compounds of formula (Ia) wherein R<sup>2</sup> is -R<sup>8</sup>-OR<sup>7</sup>, R<sup>3</sup> is -R<sup>10</sup>-N(R<sup>7</sup>)<sub>2</sub>, and R<sup>4a</sup> and R<sup>4b</sup> together form alkylidene or haloalkylidene, as discussed in more detail below.

Entry of the above amendments to the claims is respectfully requested in that the amendments are fully supported by the specification as originally filed. Reconsideration of the claimed subject matter is respectfully requested in view of the foregoing amendments and the following remarks.

### Withdrawal of Finality of Last Office Action

Applicants acknowledge the withdrawal of the finality of the previous Office Action, thereby allowing the prosecution of the application to continue.

Status of the Application

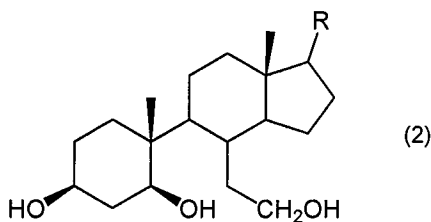
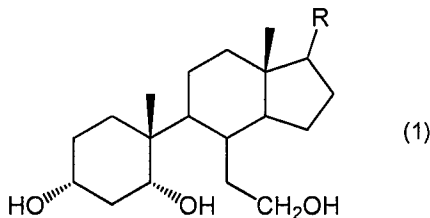
Applicants acknowledge that the Examiner's statement as to the status of the currently pending claims is correct.

Claim Rejections - 35 USC § 102

Applicants acknowledge the withdrawal of the previous rejection of Claims 1-4, 22 and 23 under 35 U.S.C. 102(b) in view of the disclosure of Madaio *et al.*<sup>1</sup>.

New Claim Rejections - 35 USC § 103

The Examiner newly rejected Claims 1-4, 22 and 23 under 35 U.S.C. 103(a) as being obvious in view of the teachings of JP 05221901 A ("Niwa"). In particular, the Examiner contends that Niwa teaches lipid-lowering compounds of the following formulae:



where R is defined therein as a hydrocarbon group, which includes C<sub>3</sub>-C<sub>10</sub> alkyls and alkenyls. In noting that Niwa does not exemplify compounds where R is alkenyl, the Examiner contends that it would have been obvious to one of ordinary skill in the art to make such compounds from the disclosure of Niwa with the reasonable expectation that such compounds would have similar lipid-lowering properties.

Claims 1-4 and 23 are cancelled, thereby rendering this rejection moot with respect to these claims. Applicants traverse this rejection for amended Claim 22 for the following reasons.

Claim 22 is amended to be directed to pharmaceutical compositions comprising a pharmaceutically acceptable excipient and a compound of formula (Ia) wherein R<sup>2</sup> is -R<sup>8</sup>-OR<sup>7</sup>, R<sup>3</sup> is -R<sup>10</sup>-N(R<sup>7</sup>)<sub>2</sub>, and R<sup>4a</sup> and R<sup>4b</sup> together form alkylidene or haloalkylidene. "Alkylidene" is

<sup>1</sup> Madaio, A. *et al.*, *Journal of Natural Products* (1990), Vol. 53, No. 3, pp. 565-572.

defined in the Specification as a straight or branched hydrocarbon radical group consisting solely of carbon and hydrogen, containing at least one double bond, having from one to seven carbon atoms, and that is attached to the rest of the molecule through a double bond, and "haloalkylidene" is defined as an alkylidene group substituted by one or more halo atoms.

Although Niwa discloses that the R group can be an alkenyl group, Applicants respectfully submit that Niwa does not fairly suggest to one skilled in the art that the R group can be an alkylidene or a haloalkylidene group which is attached to the ring through a double bond. This is particularly true, given that the only R group specifically exemplified in Niwa, *i.e.*, 6-methylheptan-2-yl, is attached to the ring by a single bond.

Furthermore, Applicants respectfully submit that there is no teaching or suggestion present in Niwa which would lead one skilled in the art to replace the 6-methylheptan-2-yl group in the compounds specifically prepared therein with an alkylidene or haloalkylidene group with any reasonable expectation that the resulting compounds would be useful as lipid-lowering agents, particularly in view of the fact that the R group in the compounds specifically disclosed as being prepared therein is unaltered by the processes disclosed therein. There is certainly no suggestion in Niwa which would lead one skilled in the art to make such replacements. Furthermore, there is certainly no suggestion in Niwa which would lead one skilled in the art to also replace the 2-hydroxyethyl group in the compounds specifically disclosed therein with an aminoalkyl group with any reasonable expectation that the resulting compounds would be useful as lipid-lowering agents, particularly in view of the fact that the intermediate used in the preparation of the Niwa compounds is a lactones instead of a lactam (the lactone ring of the intermediate is reductively opened to produce the Niwa compounds).

In view of the lack of teaching or suggestion in Niwa with respect to replacing the 6-methylheptan-2-yl group with any other group, particularly an alkylidene or haloalkylidene group and to replacing the 2-hydroxyethyl group with any other group, particularly an amino or an aminoalkyl group, Applicants respectfully submit that the teachings of Niwa do not render obvious the compounds of formula (Ia) as set forth above in amended Claim 22 and respectfully request that the rejection of Claim 22 under 35 U.S.C. 103(a) in view of Niwa be withdrawn.

#### Objection of Claims 7 and 8

The Examiner objected to Claims 7 and 8 as being dependent upon a rejected base claim. Applicants respectfully submit that in view of the amendments to Claim 7 (upon which Claim 8 depends), the objection of Claims 7 and 8 has been overcome. Accordingly, Applicants respectfully request that Claims 7 and 8 be allowed to issue forthwith.

Rejoinder of Claims 24 and 26

Upon allowance of Claim 7, Applicants respectfully request that the Examiner rejoin Claims 24 and 26 to the elected Group and that these claims be allowed to issue forthwith. In so doing, Applicants note that Claim 24 (upon which Claim 26 depends) has been amended to be commensurate in scope with the allowed Claim 7 with respect to the compounds utilized therein.

Conclusion

Favorable consideration of Claims 7-8, 22, 24 and 26 is therefore respectfully requested in view of the foregoing remarks and issuance of a Notice of Allowance thereon is earnestly solicited.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,  
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